REMARKS

Claims 1-12 are pending in the instant application. Claims 1-12 have been rejected. Claim 2 has been amended. Claim 10 has been canceled without prejudice. New claims 13 to 19 have been added. Support for these amendments is provided in the specification at, for example, pages 9-10 and Table 1, at page 28 (Example 2). No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claim 2 under 35 U.S.C. 112, second paragraph

Claim 2 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner suggests that the description of acrylic polymer as containing "substantially no alcoholic hydroxyl group in molecules" is vague.

Thus, in an earnest effort to advance the prosecution of this case, Applicants have deleted the term "substantially" from the claim.

Withdrawal of this rejection is therefore respectfully requested.

II. Rejection of Claims 1-12 under 35 U.S.C. 103(a)

Claims 1-12 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,495,159 in view of U.S. Patent 5,866,157 and Modamio et al. (International Journal of Pharmaceutics 1998 173:141-148).

Applicants respectfully traverse this rejection.

When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

(A) the claimed invention must be considered as a whole;

(B) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

(C) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

(D) reasonable expectation of success is the standard by which obviousness is determined. See MPEP 2141.

The cited combination of references fails to meet these tenets.

As acknowledged by the Examiner, U.S. Patent 6,495,159 does not teach an adhesive patch comprising bisoprolol. Further, while U.S. Patent 6,495,159 sets forth a string list of possible components for the acrylic adhesive at col. 6, lines 25-51, the reference is silent with respect to any specific examples of such copolymers. The copolymer of 2-ethylhexyl acrylate and vinyl acetate described in Example 14 of U.S. Patent 6,495,159 is also described in the instant specification at page 26 as a Comparative Example 2 and is shown in Table 1 at page 28 of the instant specification to exhibit insufficient adhesive properties and drug-content stability. As shown by these experiments, the units of acrylic polymer used in the adhesive are not a "matter of preference" as suggested by the Examiner, but rather are critical to drug stability and adhesiveness and thus the utility of the adhesive patch.

Accordingly, teachings of U.S. Patent 6,495,159, which are silent with respect to any specific examples of copolymers exhibiting stability and effective adhesion for an adhesive patch comprising bisoprolol, provide neither the required suggestion of desirability nor any reasonable expectation of success with respect to the instant claimed

invention of an adhesive patch comprising bisoprolol to render the instant claimed invention obvious.

Secondary references of U.S. Patent 5,866,157 and Modamio et al. (International Journal of Pharmaceutics 1998 173:141-148) fail to remedy deficiencies in the primary reference of U.S. Patent 6,495,159.

As acknowledged by the Examiner, the patch formulation of U.S. Patent 5,866,157 comprises organic acids and isopropyl myristate. This reference is totally silent with respect to the pressure sensitive adhesives employed in the instant invention.

Further, Applicants respectfully disagree with the Examiner's characterization of teachings of Modamio et al. Modamio et al. describe results from *in vitro* permeation experiments wherein skin samples were mounted between donor and receptor compartments of Franz glass diffusion cells and drug solution containing either celiprolol or bisoprolol was placed in the donor compartment of the cells. No where does this reference actually teach a transdermal patch containing bisoprolol, nor drug stability of bisoprolol in such a patch nor adhesiveness of such a patch.

Thus, the cited combination of references clearly fails to provide the required suggestion of desirability and any

reasonable expectation of success with respect to drug stability and adhesiveness the instant claimed invention of an adhesive patch comprising bisoprolol. Accordingly, this combination of references cannot render obvious the instant claimed invention.

Withdrawal of this rejection under 35 U.S.C. 103(a) is therefore respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Kathleen A. Tyrrell
Registration No. 38,350

Date: **October 22, 2007**

LICATA & TYRRELL P.C.
66 E. Main Street
Marlton, NJ 08053
856-810-1515